TIDI PRODUCTS
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Certified to ISO 9001:2000, EN/ISO 13485:2003, European CE Mark

K092580

510(k) Summary
TIDI® Facemask

FEB 2 8 2010

To: Whom it may concern

Date: February 12, 2010

Submitter/ Contact - Name and Address

Dion J. Brandt
Quality Manager
TIDI Products, LLC
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Neenah WI 54956
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FDA Registration Number: 2182318

Device Details:
Trade Name: *TIDI® Facemasks or Customer trade names*
Common Name: Surgical Mask
Classification Name: Mask, Surgical
Product Code: FXX
Regulation Number: 878.4040

Equivalent Legally Marketed Device:
The *TIDI® Facemasks* are similar to the predicate device in material composition, design, style and dimensions. The similarities in materials, design, style along with performance testing supports that the *TIDI® Facemasks* are substantially equivalent to the predicate device. The comparison table on the following page out-lines the similarities and any differences between the *TIDI® Facemask* and the predicate device.

K092580

Predicate Devices	510 K Number:
1) A.R. Medicom Non-Sterile Surgical Mask	K051291
2) Crosstex Isolite Surgical Mask	K012602

Device and Predicate Device Comparison

Description	***TIDI® Facemask***	**Predicate:** Non-Sterile Surgical Mask **K051291 and K012602**
Materials		
Outer layer	Polypropylene Spun-bond	Same
Filter Media	Melt-blown polypropylene	Same
Inner Layer	Polypropylene Spun-bond	Same
Nose Piece	Malleable aluminum	Same
Ear Attachment	Elastic	Same
Anti-Fog	Foam	N/A
Dimensions		
Length	7.0 inches	Same
Width	3.5 inches	Same
Design		
Style	Flat, Pleated	Same
	Fluid resistant	Same
	Elastic Ear loops	Same
Sterile	No	Same
Single Use	Yes	Same

K092580

DESCRIPTION OF THE DEVICE:

The *TIDI® Facemask*, are pleated multi-ply design which are supplied non sterile. The outer layers are made of 100% spun-bound polypropylene (SBPP). The filter media is composed of 100% melt-blown polypropylene (MBPP). The inner layer is made of either 100% SBPP or 100% medical grade tissue paper. The ear loops are made of latex free elastic. The nosepieces are made of malleable aluminum, and can be supplied with an anti fog strip made of polyester urethane foam. All materials used in the construction of the mask are being used in currently marketed devices. The mask covers the nose and mouth, and is secured to the face using the attached ear loops. The *TIDI® Facemasks* are intended to be worn by operating room personnel during surgical procedures to protect both the surgical patient and the operating personnel from transfer of micro-organisms, body fluids and particulate material.

The following is a list of models of the *TIDI® Facemask*s with a description.

Model 9010 -This is the standard facemask model with ear loop attachments.

Model 9020-This facemask model is supplied with an anti-fog strip of polyurethane foam. The foam is attached over the nose wire on the inside of the mask.

INTENDED USE:

The *TIDI® Facemask* intended use is: Surgical mask are devices that are intended to be worn by operating room personnel during surgical procedures to protect both the surgical patient and the operating personnel from transfer of micro-organisms, body fluids and particulate material.

K092580

Device and Predicate Device Technical Characteristics:

Description	TIDI® Facemask	Predicate Device K012602 Crosstex® Ultra Fluid Resistant No-Fog® Ear Loop Face Mask	Predicate Device K051291 Safe+Mask® Premier Elite Ear loop Mask
Material Composition Type of fabric:			
Outer Layer	Polypropylene Spun-bond	Polypropylene Spun-bond	Polypropylene Spun-bond
Filter Media	Melt-blown polypropylene	Melt-blown polypropylene	Melt-blown polypropylene
Inner Layer	Polypropylene Spun-bond	Polypropylene Spun-bond	Polypropylene Spun-bond
Other Materials:			
Nose Piece:	Aluminum	Aluminum	Aluminum
Ear Attachment:	Elastic	Elastic	Elastic
Anti-Fog	Polyester Urethane foam	Polyester Urethane foam	none
The difference of the anti fog material is the polyester urethane foam. The polyester foam material has been used in medical application on facemask for an anti-fog strip without any toxicity or biological compatibility issues. It has been proven to be non-toxic, non-sensitizing, and non-irritating.			
Specification and Dimensions:			
Dimensions: **Length:**	7.0 inches	7.0 inches	7.0 inches
Width:	3.5 inches	3.5 inches	3.5 inches
Design Features:	Ear Loop	Ear Loop	Ear Loop
Mask Style:	Flat Pleated	Flat Pleated	Flat Pleated

K092580

Nonclinical Tests Performed for Determination of Substantial Equivalents are as Follows:

The following is a list of test methods for the *TIDI® Facemask* in accordance with ASTM 2100 specification for surgical masks. It was our conclusion that testing was conducted and met the specified acceptance criteria of **ASTM F 2100-07** ***Standard Specification for Performance of Materials Used in Medical Face Mask.***

Performance Characteristics	Face Mask Requirements by Performance Class (ASTM F 2100-07)			TIDI® Facemask Test Results Summary
	Low Barrier	Moderate Barrier	High Barrier	
Bacterial Filtration Efficiency Performance (%) (ASTM 2101)	≥95	≥98	≥98	>99.9
Differential Pressure (Delta-P) (mm H_2O/cm^2) (MIL-M 36954C)	<4.0	<4.0	<4.0	3.4
Sub-micron Particulate Filtration Efficiency at 0.1 micron Performance (%) (ASTM F 2299)	Not required	≥98	≥98	99.6
Resistance to penetration by synthetic blood, Minimum pressure in mmHg for pass results. (ASTM F 1862)	80	120	160	Pass @ 80 mm Hg
Flammability Class (16CFR Part 1610)	Class 1	Class 1	Class 1	Class 1

Conclusion:

The *TIDI® Facemask* has the same intended use and technological characteristics as the predicate devices. Product testing and FMEA risk analysis performed did not identify any other risks on the safety or effectiveness associated with surgical masks, other then identified in the Guidance for Industry and FDA Staff: Surgical Masks- Premarket Notification [510(k)] Submission; Guidance for Industry and FDA issued on: March 5, 2004. The *TIDI®* Facemask are substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Ms. Dion J. Brandt
Quality Manager
TIDI Products, LLC
570 Enterprise Drive
Neenah, Wisconsin 54956

FEB 23 2010

Re: K092580
Trade/Device Name: TIDI® Facemask
Regulation Number: 21CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: II
Product Code: FXX
Dated: December 7, 2009
Received: December 7, 2009

Dear Ms. Brandt:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Anthony D. Watson, BS, MS, MBA
Director
Division of Anesthesiology, General Hospital,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K092580

Medical Devices

Indications for Use Form

Indications for Use

510(K) Number (if Known): _K092580_____

Device Name: TIDI® Facemask

Surgical mask are devices that are intended to be worn by operating room personnel during surgical procedures to protect both the surgical patient and the operating personnel from transfer of micro-organisms, body fluids and particulate material.

Prescription use_____ AND/OR Over- The Counter Use ___X__
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Elizabeth D. Claverie Wills

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K092580